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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,493	11/20/2001	Herath Mudiyanselage Athula Chandrasiri Herath	2543-1-024	8554

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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 09/23/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/988,493	Applicant(s) CHANDRASIRI HERATH ET AL.	
	Examiner Young J. Kim	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to a method of diagnosing breast cancer via 2-D gel analysis, classified in class 204, subclass 450.

II. Claims 8-19, drawn to a method of diagnosing breast cancer via quantitating breast cancer protein, classified in class 435, subclass 500.

III. Claims 20 and 21, drawn to a pharmaceutical composition, classified in class 424, subclass 1.49.

IV. Claims 22-24, drawn to a method of treating breast cancer via nucleic acid (antisense) therapy, classified in class 514, subclass 44.

V. Claims 25-27 and 38, drawn to a method of screening for agent interacting with a breast cancer protein, classified in class 530, subclass 387.1.

VI. Claims 28-30 and 39-41, drawn to an *in vitro* method of modulating the expression of a breast cancer protein, classified in class 436, subclass 512.

VII. Claims 31-37, drawn to an *in vivo* method of modulating the expression of a breast cancer protein, classified in class 424, subclass 130.1.

VIII. Claims 42-44, drawn to a prognostic method of breast cancer on an array, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and IV-VIII are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve different elements which require different modes of operation to achieve the different functions. For example, the method of Group I requires the use of gel electrophoretic separation of proteins in order to diagnose breast cancer proteins while none of the remaining methods employ this method. The method of Group II is drawn to a method of diagnosing breast cancer via quantitating the level of breast cancer protein while the methods of IV-VIII are drawn to methods that achieve patentably different effects. For example, the methods of IV and VIII requires the use of nucleic acid for therapy/analysis while the method of II is simply drawn to quantitating the level of breast cancer protein. Similarly, the methods of V-VII are drawn to a method which interacts with or modulates the expression of the breast cancer protein, the methods of which involve analysis and steps which are not coextensive in search with the method of II which only involves the quantitation of a protein level. While methods of IV and VIII involve the use of nucleic acid(s), the method of IV is drawn to a therapy of breast cancer which involves far more analysis and steps which are not coextensive in search with the method of VIII which requires a group of nucleic acid for the purpose of hybridization/detection of breast cancer. The method of IV is also not related to methods of V-VII because the method of IV employs nucleic acid molecules and thus not useable together with the methods of V-VII. Although the methods of VI and VII are both drawn to a method of modulating the expression of breast cancer protein, the methods are considered to be patentably distinct, requiring added search burden because the method of VI is drawn to an *in vitro* study

while the method of VII is drawn to an *in vivo* study which requires far more analysis and steps which are not coextensive in search. Such justification is deemed proper because not all *in vitro* studies behaves the same *in vivo*, and the analyses and state of the art are not coextensive, all of which would amount to an added search burden. Finally, the methods of VI and VII are not useable together with the method of VIII which requires an array of nucleic acids.

Invention III is unrelated to Inventions I, II, and IV-VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of I, II, and IV-VIII do not require the pharmaceutical product of III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Single Combination Election Requirement Applicable to Groups I-III & VIII

In addition, each Group detailed above reads on combination of patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group, Applicants must further elect a single combination of amino acid or nucleotide sequence.

Examination will be restricted to only the elected combination of sequences (See MPEP 803.04 (c)).

A Single Sequence Election Requirement Applicable to Groups IV-VII

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group, Applicants must further elect a single amino acid or nucleotide sequence.

Examination will be restricted to only the elected sequence (See MPEP 803.04 (a)).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is not longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was not made to request an oral election to the above restriction requirement due to the complex nature of the requirement (MPEP § 812.01).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through

Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (703)-308-3905. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

9/17/03

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
9/22/03